

EC functions in the same way as ordinary birth control pills and can not interrupt an established pregnancy. Unfortunately, it seems that the FDA is treating Plan B® differently than other forms of contraception and differently than other OTC applications. Even the FDA's own staff finds the treatment of the Plan B® application to be unusual and unacceptable. There is no scientific explanation for why the FDA has subjected the Plan B® OTC application to a different and more rigorous standard than other drugs, only a political one.


Dr. John Jenkins, Director of the Office of New Drugs at the FDA, stated that "the data submitted by the sponsor in support of non-prescription use of Plan B® are fully consistent with the Agency's usual standards for meeting the criteria for determining that a product is appropriate for such use" and that the agency had not previously distinguished the safety and efficacy of birth control among different ages. We believe, as Dr. Jenkins does, that the "available data clearly support a conclusion that Plan B® meets the statutory and regulatory requirements for availability without a prescription for all age groups." Dr. Jenkins goes on to say that "such a conclusion is consistent with how the Agency has made determinations for other OTC products, including other forms of contraception available without a prescription." When the FDA's own leadership acknowledges that Plan B has been treated differently, it is time for the FDA to take a step back, assess the situation, and commit to moving towards restoring credibility and public trust.

As the new Acting Commissioner, you have the opportunity to set the FDA back on the right track by following the science. Science tells us that Plan B® should be made available to women of all ages without a prescription. Turning this process over to rulemaking has fully exposed the fact that what started off as scientific inquiry has only become a question of politics. The public wants a reason to be proud of the FDA. It is time for the FDA to stop playing politics with women's lives and return to the days where an obligation to protect the public health was taken seriously. The time has come to restore public confidence in the FDA and to approve the Plan B® OTC application so that women of all ages can have access to EC without delay.

Sincerely,


Anna Franks, President/CEO


Dr. Sara Cate, Medical Director


Gina Popovic, Public Policy Director